Guidance for Staff, Industry, and Third Parties

Implementation of Third Party Programs Under the FDA Modernization Act of 1997 - June 2000

Draft Guidance – Not for Implementation

The purpose of this document is to solicit comments for proposed changes to Guidance for Staff, Industry, and Third Parties Implementation of Third Party Programs Under the FDA Modernization Act of 1997, October 30, 1998

Draft released for comment on June 12, 2000

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Division of Small Manufacturers Assistance
Office of Health and Industry Programs

Preface

Public Comment:

Comments and suggestions regarding this draft document should be submitted by September 1, 2000 to Docket No. 98N-0331, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, (HFA-305), Room 1061, Rockville, MD 20852

Additional Copies:

World Wide Web/CDRH home page: http://www.fda.gov/cdrh/thirdparty or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1160 when prompted for the document shelf number. In addition, copies can be obtained on 3.5" IBM formatted disks. To request a copy on disk, FAX a request to DSMA, Attention: Publications at 301-443-8818.

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Guidance for Staff, Industry, and Third Parties Implementation of Third Party Programs Under the FDA Modernization Act of 1997- June 2000

I. Purpose

The purpose of this guidance[1] is to assist those who are interested in participating in this program, either as persons accredited to perform premarket notification [510(k)] reviews (Accredited Persons) or as applicants pursuing clearance of 510(k) submissions consistent with the Food and Drug Administration Modernization Act of 1997 (FDAMA), as well as Food and Drug Administration (FDA) staff responsible for implementing the program.

II. Introduction

In accordance with FDAMA, FDA established criteria to accredit or deny accreditation to persons who request to review reports submitted under section 510(k) of the Federal Food, Drug and Cosmetic Act (the act) and make recommendations to FDA regarding the initial classification of devices under section 513(f)(1) of the act. FDA published those criteria in the FEDERAL REGISTER on May 22, 1998 (63 FR 28388). In addition, FDA issued a guidance document on October 30, 1998 to provide guidance for staff, industry, and third parties on implementation of the third party program. FDA announced the availability of that guidance document on November 2, 1998 (63 FR 58746) and a copy can be found at http://www.fda.gov/cdrh/thirdparty. FDA is issuing this draft guidance in an effort to expand the third party program to include criteria that would provide for the review of additional moderate risk (Class II) devices.

In the first 17 months that the FDAMA third party program has been in effect, 28 companies have used third parties to review a total of 54 510(k) submissions. During that same period, nearly 2,000 510(k) submissions from approximately 800 companies were eligible for third party review. Thus, industry use of the

[1] This document is intended to provide guidance. It represents the agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

third party approach has been low. This approach has typically yielded rapid marketing clearance decisions, however. In fiscal year 1999, the average total elapsed time between a third party's receipt of a 510(k) submission and FDA's substantial equivalence determination was 57 days. The portion of this time that occurred between FDA's receipt of the third party's recommendation and FDA's determination averaged just 15 days.

Both the agency and the industry have been disappointed that the third party program has not been used more. FDA's current policy permits third party review of only those Class II devices for which some device-specific guidance or recognized consensus standards exist. The agency instituted that policy when it implemented the program in order to ensure that there would be consistency among different third party reviewers and to enhance the timeliness of the agency's review process once a recommendation is submitted by a third party. FDA believes the extremely short time frames that have been associated with third party reviews are, in part, attributable to this policy. However, in an effort to expand use of the third party program, the agency is proposing to initiate a pilot that will allow third party review of any device that is not prohibited from such review under the statute. This guidance is intended to explain how the agency intends to implement such a pilot and the measures it will institute to address continued concerns about consistency and timeliness. The draft guidance includes significant portions of the current guidance relating to the third party program that are not being changed in order to provide a single document that would contain most of the relevant information for staff, industry, and third parties. After FDA reviews comments and finalizes this guidance, it will supersede the October 30, 1998 guidance currently in effect.

A. Background

Purpose of Section 510(k)

The current regulatory framework for medical devices was created by the Medical Device Amendments of 1976 (the amendments) to the act, as amended by the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the FDA Modernization Act of 1997. Section 513(a) of the act [21 U.S.C. 360c(a)], establishes three device classes and directed FDA to publish regulations classifying each device then on the market into one of those three classes. Classification is based on the level of control necessary to provide reasonable assurance of the safety and effectiveness of a device. Class I devices are subject only to general controls, which include establishment registration, device listing, records and reports, and current good manufacturing practices requirements. Class II devices are subject to general controls and special controls, such as promulgation of performance standards, postmarket surveillance, patient registries, and dissemination of guidelines and recommendations. Class III devices are subject to premarket approval, special controls, and general controls. A

preamendments Class III device is not required to receive premarket approval until the effective date of a regulation calling for premarket approval promulgated under section 515 (b)(2) of the act.

Section 513(f) of the act contains special classification provisions for postamendments devices. A device introduced on or after the amendments' enactment date (May 28, 1976) is automatically in Class III and must receive premarket approval or be reclassified into Class I or II before marketing unless it is substantially equivalent to a legally marketed predicate device (a device marketed before the amendments' enactment, or a device introduced after the amendments' enactment that FDA has reclassified from Class III into Class I or II) for which premarket approval is not required.

Section 510(k) of the act provides a means to ensure that manufacturers do not intentionally or unintentionally circumvent the automatic classification provisions of section 513(f). Under section 510(k), a person who intends to begin introduction of a device into commercial distribution in the United States is required to submit a 510(k) to FDA at least 90 days in advance of commercial distribution, unless the agency has exempted the device from this premarket notification requirement. FDA reviews 510(k)s to determine if a new device is substantially equivalent to a predicate device. A device determined by FDA to be substantially equivalent is in the same class and may be introduced to the market subject to the same regulatory controls as its predicate device. Before marketing the device, the manufacturer must receive an order from FDA, in the form of a letter, declaring the device to be substantially equivalent. A device determined to be not substantially equivalent remains in Class III and must receive premarket approval or be reclassified before it is marketed.

The meaning of the term "substantially equivalent" is addressed in section 513(i) of the act. Substantial equivalence means that a device: (1) has the same intended use and the same technological characteristics as a legally marketed device; or (2) has the same intended use and different technological characteristics, but there is information in the 510(k) demonstrating that the device is as safe and effective as a predicate device and the device does not raise different questions of safety and effectiveness than the predicate device. Substantial equivalence determinations are made by scientific review staff within the Center for Devices and Radiological Health (CDRH). Determinations are based primarily upon information provided in a manufacturer's 510(k). FDA has published regulations (21 CFR part 807, subpart E) specifying 510(k) content and procedures. FDA also has developed numerous guidance documents and policy memoranda for the 510(k) program that are available on the CDRH Home Page, on the World Wide Web, or from the Division of Small Manufacturers Assistance (DSMA), as discussed later in this document.

Third Party Review Pilot Program

In 1996, FDA began a voluntary third party review pilot program. The purpose of the pilot program was to: (1) provide manufacturers of eligible devices an alternative review process that could yield more rapid marketing clearance decisions; and (2) enable FDA to target its scientific review resources at higher-risk devices, while maintaining confidence in the review by third parties of low-to-moderate risk devices. Under the program, all Class I devices that were not exempt from 510(k) at that time and 30 Class II devices were eligible for third party review. During the first 18 months of the pilot program, FDA received twenty-two 510(k)s that were reviewed by Recognized Third Parties. In contrast, during the same period, FDA received more than 1,300 510(k)s for third party eligible devices that were not reviewed by third parties.

FDAMA

FDAMA was signed into law by the President on November 21, 1997. Section 210 of FDAMA essentially codified and expanded the pilot program by establishing a new section (523) of the act that directs FDA to accredit third parties (Accredited Persons) in the private sector to conduct the initial review of 510(k)s for low-to-moderate risk devices. FDAMA specifies that an Accredited Person may not review any Class III device or any Class II device that is permanently implantable, life-supporting, life-sustaining, or for which clinical data are required. (Section 523 sets limits on the number of Class II devices that may be ineligible for Accredited Person review because clinical data is required.) In addition, FDAMA requires FDA to respond to requests for accreditation in 60 days. On November 21, 1998 the agency began accepting reviews by Accredited Persons. FDAMA requires FDA to make a determination regarding those reviews within 30 days.

On September 23, 1998, FDA made available a list of persons accredited to conduct 510(k) reviews for certain devices. Accredited Persons were not eligible to begin to review applications until they successfully completed a training session. Beginning on November 21, 1998, trained Accredited Persons could submit reviews and recommendations to the agency.

B. Outline of the Accredited Persons Review Program

Purpose and Nature of Program

The purpose of this program is to implement section 523 of the act by accrediting third parties (Accredited Persons) to conduct the initial review of 510(k)s for selected low-to-moderate risk devices. The Third Party Review Pilot Program terminated on November 21, 1998, which is when FDA began accepting reviews and recommendations from trained Accredited Persons.

The Accredited Persons Program is intended to enable FDA to target its scientific review resources at higher-risk devices, while maintaining a high degree of confidence in the review process by using Accredited Persons to assess low-to-moderate risk devices and at the same time provide manufacturers of eligible devices an alternative review process that may yield more rapid 510(k) decisions.

In accordance with the requirements of section 523 and based on experience with the Third Party Review Pilot Program, FDA's initial implementation of the Accredited Person Program included a number of features designed to maintain a high level of quality in 510(k)s reviewed by Accredited Persons and to minimize risks to the public. These include:

- Exclusion of all Class III devices and any Class II devices that are permanent implants, life-supporting/life-sustaining, or which require clinical data (FDAMA limits the number of Class II devices that may be ineligible for Accredited Person review because of the need for clinical data.);

- FDA assessment, recognition, and training of Accredited Persons before their participation in the program;

- Personnel qualifications for Accredited Persons equivalent to the level within the Center for Devices and Radiological Health's (CDRH) Office of Device Evaluation;

- Criteria to prevent potential conflicts of interest for Accredited Persons that might affect the review process;

- FDA oversight of Accredited Person reviews/recommendations and FDA's continued responsibility for the issuance of 510(k) decisions;

- Provisions for FDA to make onsite visits on a periodic basis to each Accredited Person to audit performance and for inspection of records, correspondence, and other materials relating to Accredited Person review;

- FDA monitoring and evaluation of the program to ensure that Accredited Persons are substantially in compliance with the requirements of section 523 of the act and do not pose a threat to public health;

- Continued applicability of all other regulatory controls (e.g., medical device reporting of post-marketing adverse events) applicable to devices included in the program;

- Prohibition against forum shopping by submitters of 510(k)s; and

- The initial phase of implementation has also included reliance by Accredited Persons on use of review guidance and/or recognized standards to ensure accurate and timely review.

FDA now intends to encourage more widespread use of the third party program by accepting reviews from Accredited Persons of devices for which there is no device-specific review guidance under the following circumstances. An Accredited Person may review a Class II device that does not have device-specific guidance if:

1) The Accredited Person has previously completed three successful 510(k) reviews under the third party program. This should include at least one 510(k) review that was in the same or similar medical specialty area as the device the Accredited Person now intends to review. The prior 510(k) reviews can be for Class II devices that have device-specific guidance or for Class I devices;

2) The Accredited Person contacts the appropriate CDRH Office of Device Evaluation (ODE) Branch Chief (or designee) before initiating a 510(k) review for a Class II device that does not have a device-specific guidance to confirm that the Accredited Person meets the criteria in paragraph 1 above for review and to identify pertinent issues and review criteria related to this type of device; and

3) The Accredited Person prepares a summary documenting the discussions and submits the summary of those discussions to ODE.

The discussion and summary would not be binding on the agency or the Accredited Person. The pre-submission discussions and the creation of a record of those discussions will help FDA ensure the consistency and timeliness that can be provided by device-specific guidances. In addition, the FDA may utilize such documentation to ensure consistency in its own interactions with different Accredited Persons and regular submitters. Moreover, the record of these discussions will help FDA determine whether there is a need to issue device-specific guidance and could facilitate future development of those documents.

The purpose of a review by an Accredited Person is to evaluate a manufacturer's 510(k), document the review, and make a recommendation to FDA concerning the substantial equivalence of the device or initial classification under 513(f)(1). FDA provides information on procedures and criteria that it uses for 510(k) reviews in general guidance and in a training program that was made available by FDA before commencement of the program. Accredited Persons may access the CDRH Home Page for general information on regulatory guidance and on FDAMA (see Section V). Accredited Persons may also consult existing FDA guidance documents, such as "Premarket Notification 510(k) - Regulatory Requirements for Medical Devices" (August 1995), "In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions" (January 1997), "Guidance on the Recognition and Use of Consensus Standards" (February 1998), "Guidance on the Use of Standards in Substantial Equivalence Determinations"(March 2000) and "Determination of Intended Use for 510(k) Devices - Guidance for Industry and CDRH Staff" (January 1998). These publications provide an overview of device regulations, FDA requirements concerning 510(k) content and format, a description of the 510(k) review process, important policy memoranda, and additional information useful to manufacturers and Accredited Persons (see Section V).

FDA encourages both Accredited Persons and those seeking accreditation to be familiar with the information outlined in these publications and in subsequent guidance. The general guidance, any device-specific review guidance made available by FDA, and pre-submission discussions will assist the Accredited Persons in producing adequate reviews that the agency can process in a timely manner.

Devices Eligible for Accredited Person Review

Accredited Persons may not review:

1) a Class III device;

2) a Class II device which is intended to be permanently implantable or life sustaining or life supporting; or

3) a Class II device which requires clinical data in the report submitted under section 510(k). (Section 523 sets limits on the number of Class II devices that may be ineligible for Accredited Person review.)

Any 510(k) for a Class II device for which clinical data are needed to make a determination of substantial equivalence will continue to be subject to primary review by FDA and will not be processed by FDA under the special procedures for this program. The decision to require clinical data is a matter of

judgment that is often dependent on the nature of any differences between the new device and the device to which it is being compared (e.g., an additional specific indication for use). Manufacturers and Accredited Persons seeking guidance on the need for clinical data in a 510(k) should consult FDA's guidance documents and may also contact the appropriate review division in CDRH's Office of Device Evaluation.

On May 20, 1998 FDA made available on the World Wide Web (WWW) a list of 50 Class I devices and 104 Class II devices that are eligible for review by Accredited Persons. FDA included all Class I devices not exempt from premarket notification, because the agency determined that general guidance provided by CDRH is a sufficient basis for third party review of these relatively low risk devices. However, the decision to include Class II devices was partly dependent on the existence of device-specific guidance and/or FDA recognized standards. In an effort to encourage use of the Accredited Persons Program, FDA now intends to include in this expansion pilot all Class II devices regulated by the CDRH that the agency believes are not prohibited from third party review under the statute, regardless of whether device specific guidance is available for the device. The pilot program will also include devices for which there is a limited exemption from 510(k). If a new version of a device requires a 510(k) because the change exceeds the limitation, that device is eligible for third party-review unless it can not be reviewed by a third party because of the statutory exclusions under section 523 of the act. A list of devices FDA intends to include in the expansion pilot (except for the "exempt" devices referred to above) is available on the CDRH web site at http://www.fda.gov/cdrh/thirdparty. As with the current Accredited Persons Program, the expansion pilot will not include 510(k) s that require multi-Center review (e.g., 510(k) s for drug/device combination products) and devices for which the Center for Biologics Evaluation and Research has primary responsibility for review.

The pilot will start after FDA reviews comments and finalizes this guidance. The agency intends to review the pilot program 12 months after it begins to see if the number of third party 510(k)s has increased significantly, if the timeliness of review is maintained, and to consider whether particular divisions within FDA’s Office of Device Evaluation are devoting disproportionate staff time to pre-submission discussions with Accredited Persons. The agency reserves the option to stop or reevaluate the pilot at any time it determines that additional work load generated by third party consultations compromises FDA’s ability to review other applications or the agency has reason to believe the quality of the reviews is significantly diminished by lack of device-specific guidance.

In addition, the agency emphasizes that the expansion of the program is not intended to diminish the obligation of Accredited Persons to consult guidance

documents and/or standards recognized by FDA whenever these are available. (See Section V.)

Accreditation/Withdrawal of Persons

FDA has established the criteria and acts as the accreditor for Accredited Persons under FDAMA. FDA only accredits persons who demonstrate that they meet the criteria published in the FEDERAL REGISTER notice of May 22, 1998, and addressed in Section II.B. of this document, Qualifications of Accredited Persons. There is no limit on the number of qualified persons who may become Accredited Persons. Applicants may apply to be Accredited Persons for the review of a broad range of device types or to review specific types of devices. In all cases, FDA accredits only applicants with qualified personnel and stringent conflict of interest standards. In addition, FDA considers accreditation applications from both domestic and foreign persons. However, all applications and communications with the agency and all documentation pertaining to the review of a 510(k) should be in English and made by a United States representative of the Accredited Person so that the agency may do an adequate review and efficiently communicate with applicants.

CDRH maintains and makes public a list of Accredited Persons eligible to submit 510(k) reviews to FDA. This list provides the name, contact person, address and telephone number of the Accredited Person. The list of Accredited Persons was made available to the public on the World Wide Web at the CDRH Home Page on September 23, 1998 (see Section V). The list is updated routinely. In addition, CDRH has established a "Third Party" link at http://www.fda.gov/cdrh/thirdparty on the CDRH Home Page that provides immediate access to information about the Accredited Persons Program including a copy of this guidance and the list of eligible devices.

In accordance with section 523(b)(2), FDA may suspend or withdraw accreditation, after providing notice and opportunity for an informal hearing, when an Accredited Person:

1) is substantially not in compliance with section 523;

2) fails to act in a manner consistent with the purposes of section 523; or

3) poses a threat to public health.

In addition, it is a prohibited act under section 301(y)(1) for an Accredited Person to:

1) submit a report that is false or misleading;

2) disclose confidential information or trade secrets without the submitter's consent; or

3) receive bribes or perform a corrupt act.

Consistent with current practice, FDA will continue to accept 510(k)s from third parties that have not been accredited, but will treat the submission in the same manner as a 510(k) submitted directly from a manufacturer.

Persons that wish to become accredited should submit applications to FDA. A decision to accredit or not to accredit will be made within 60 days of the receipt of an application. However, FDA does not accept 510(k) reviews and recommendations from Accredited Persons that have failed to have at least one designated employee attend an FDA training session for Accredited Persons. FDA plans to provide training on a periodic basis for persons newly accredited and to augment initial training conducted on October 14-16, 1998. Applications should be submitted to: Accredited Person Program, Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, 1350 Piccard Drive, Rockville, Maryland 20850 USA. For purposes of this program, applicants should use the format for applications described in Section IV.

Qualifications of Accredited Persons

To be accredited by FDA, applicants must demonstrate that they have the appropriate qualifications and facilities to conduct competent 510(k) reviews and have instituted effective controls to prevent any conflict of interest or appearance of conflict of interest that might affect the review process.

In accordance with section 523(b)(3), to be accredited by FDA, an applicant must, at a minimum, have the following qualifications:

1) an Accredited Person may not be a Federal Government employee;

2) an Accredited Person shall be an independent organization not owned or controlled by a manufacturer, supplier, or vendor of devices and have no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor;

3) an Accredited Person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation;

4) an Accredited Person shall not engage in the design, manufacture, promotion, or sale of devices;

5) an Accredited Person shall operate in accordance with generally accepted professional and ethical business practices and agree in writing that as a **minimum** it will:

   (i) certify that reported information accurately reflects data reviewed;

   (ii) limit work to that for which competence and capacity are available;

   (iii) treat information received, records, reports, and recommendations as proprietary information;

   (iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

   (v) protect against the use of any officers or employees to conduct reviews when that person has a financial conflict of interest regarding the device, and annually make available to the public disclosures of the extent to which the Accredited Person, officers and employees have maintained compliance with requirements relating to financial conflicts of interest.

In addition to the minimum requirements for Accredited Persons set forth in FDAMA, FDA has established the following qualifications (see 63 FR 28388, May 22, 1998):

1) Personnel.

   FDA expects to consider several factors with respect to personnel qualifications when it considers accrediting applicants. These include:

   a) whether personnel have demonstrated knowledge of:

      - the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)

      - the Public Health Service Act (42 U.S.C. 201 et seq.)

      - regulations implementing these statutes, particularly 21 CFR parts 800-1299.

b) whether the applicant:

- has established, documented, and executed policies and procedures to ensure that 510(k)s are reviewed by qualified personnel, and whether it will maintain records on the relevant education, training, skills, and experience of all personnel who contribute to the technical review of a 510(k);

- has clear, written instructions for duties and responsibilities with respect to 510(k) reviews available to its personnel;

- has employed personnel who, as a whole, are qualified in all of the scientific disciplines addressed by the 510(k)s that the Accredited Persons accept for review;

- has identified at least one individual who is responsible for providing supervision over 510(k) reviews and who has sufficient authority and competence to assess the quality and acceptability of these reviews; and

- is prepared to conduct technically competent reviews at the time of requesting accreditation by FDA.

c) for appropriate review of a particular Class II device, FDA will expect specialized education or experience to assure a technically competent review.

Information on the general education and experience that FDA requires of its scientific review personnel is included in the appendix, Qualification Standards for FDA Reviewers. An applicant may adopt these criteria as one means of ensuring that its personnel with primary responsibility for review of a 510(k) for a Class I device have appropriate education and experience. An applicant may develop and apply alternative criteria that result in personnel with appropriate education and experience necessary to review 510(k)s for Class I devices.

2) Facilities.

FDA expects to accredit persons that have the capability to interface with FDA's electronic data systems, including the FDA Home Page, CDRH Home Page, and the CDRH Facts-On-Demand system. At a minimum, this would include a computer system with a modem and an independent facsimile machine. FDA will rely extensively on the use of FDA's electronic data systems for timely dissemination of guidance

documents to Accredited Persons and other interested parties (see Section V).

3) Prevention of Conflicts of Interest.

FDA expects Accredited Persons to be impartial and free from any commercial, financial, and other pressures that might present a conflict of interest or an appearance of conflict of interest. To that end, when deciding whether to accredit a person, FDA will consider whether the person has established, documented, and executed policies and procedures to prevent any individual or organizational conflict of interest, including conflicts of contractors or individual contract employees.

Although it is not feasible to identify all of the circumstances that would raise concerns about conflicts of interest, the most common conditions that would indicate a potential conflict of interest are:

(a) the Accredited Person is owned, operated, or controlled by a device manufacturer or distributor;

(b) the Accredited Person or any of its personnel involved in 510(k) reviews has an ownership or other financial interest in any medical device, device manufacturer, or distributor;

(c) the Accredited Person or any of its personnel involved in 510(k) reviews participates in the design, manufacture, or distribution of any medical device;

(d) the Accredited Person or any of its personnel involved in 510(k) reviews provides consultative services to any device manufacturer or distributor regarding specific devices;

(e) the Accredited Person or any of its personnel involved in 510(k) reviews participates in the preparation of 510(k)s;

(f) in reviewing a 510(k) the Accredited Person uses personnel who were employed within the last twelve months by the firm who submitted the 510k for review; or

(g) the fees charged or accepted are contingent or based upon the recommendation for initial classification made by the Accredited Person.

An Accredited Person may assess a fee for its services. An Accredited Person also may conduct other activities, such as objective laboratory

testing of devices or assessment of conformance to standards, if those other activities do not affect the impartiality of 510(k) reviews. In addition, an Accredited Person may provide general information on 510(k) requirements to permit the submitter to improve the organization or content of a 510(k) that it is reviewing.

When an Accredited Person uses the services of a contractor in connection with a 510(k) review, the Accredited Person is responsible for the contracted work of its contractor. The Accredited Person is to assure that the contractor meets the same criteria for freedom from conflicts of interest as the Accredited Person.

Information on the conflict of interest standards FDA applies to its own review personnel is included in the appendix, Standards for Ethical Conduct for Employees of the Executive Branch. An applicant may adopt these standards as one means of safeguarding its operations against conflicts of interest.

4) Training.

The criteria established by FDA in the FEDERAL REGISTER notice of May 22, 1998, require Accredited Persons to certify in their application that they will have designated employees attend FDA training for Accredited Persons. FDA conducted initial training for Accredited Persons on October 14-16, 1998 and plans to provide such training on a periodic basis for persons newly accredited.

Accredited Persons are to complete training before conducting any 510(k) reviews under the program. FDA does not accept 510(k) reviews and recommendations from Accredited Persons that have failed to have at least one designated employee attend an FDA training session for Accredited Persons.

Identification of an Accredited Person

Submitters of 510(k)s interested in using an Accredited Person should access the CDRH Home Page for a list of Accredited Persons and the name and address of each Accredited Person's contact. Persons that do not appear on the List of Accredited Persons are not eligible to review 510(k)s under section 523 of the act.

FDA is maintaining and making publicly available a list of all Accredited Persons. FDA believes that it is beneficial for manufacturers to interact with multiple Accredited Persons. If FDA monitoring of the program reveals that manufacturers are developing business relationships with Accredited Persons that call into question the independence or objectivity of the Accredited

Person, FDA will consider implementing a process that limits the submitter's choice of Accredited Persons for a specific review. Business relationships that may undermine the independence or objectivity of an Accredited Person include contracts between a manufacturer and an Accredited Person that represent a significant share of the Accredited Person's income over the period of the contract, such that continuation or termination of the contract may create the appearance of an undue financial influence.

FDA may refuse to process a 510(k) and consider the accompanying Accredited Person review under section 523 if it appears to FDA that the submitter has engaged in forum shopping in order to find an Accredited Person who is most likely to recommend clearance of the submitter's 510(k). It is not feasible to identify or state categorically all of the criteria for evaluating whether a submitter has forum shopped. However, if FDA determines that a submitter has obtained reviews of the same 510(k) from more than one Accredited Person, there will be a presumption of forum shopping and FDA may refuse to provide special processing of a submitter's 510(k) unless the submitter can explain to FDA's satisfaction why the circumstances do not indicate forum shopping. If experience with the program indicates that submitters are engaging in such forum shopping, FDA will consider implementing procedures that require additional limits on and monitoring of initial contacts between manufacturers and Accredited Persons.

Participation in the program is entirely voluntary. Submitters may continue to submit 510(k)s directly to FDA. Submitters may also employ the assistance of third parties other than those accredited by FDA, but only 510(k)s reviewed by Accredited Persons will be eligible for review within 30 days under section 523.

Review Materials to be Submitted to FDA by an Accredited Person

Upon completion of its review of a 510(k), an Accredited Person should submit the following documentation to FDA, in duplicate, in order to expedite timely agency review of the Accredited Person's recommendation:

1. A cover letter signed by the Accredited Person's contact person clearly identifying: the purpose of the submission; the name and address of the Accredited Person; FAX and telephone number of the contact person; the name and address of the manufacturer/submitter; the name of the device (trade name, common or usual name, FDA classification name, classification regulation number and product code); the Accredited Person's recommendation with respect to the substantial equivalence of the device; and the date the Accredited Person first received the 510(k) from the manufacturer/submitter.

2. A letter signed by the manufacturer/submitter authorizing the Accredited Person to submit the 510(k) to FDA on its behalf and to discuss its contents with FDA.

3. If the Accredited Person is reviewing a product that is not the subject of device-specific guidance, they should submit a statement that the Accredited Person has previously completed three successful 510(k) reviews under the third party program, identification of the 510(k) that was in the same or similar medical specialty area as the device it has reviewed, and a copy of the summary of the pre-submission discussion that occurred with the appropriate branch chief or designee.

4. The manufacturer's/submitter's complete 510(k) conforming to FDA's established requirements relating to content and format of such submissions.

5. A complete review of the 510(k), signed by all personnel who conducted the review and by an individual responsible for supervising 510(k) reviews, with a recommendation concerning the substantial equivalence of the device.

6. A certification that reported information accurately reflects data reviewed.

7. Any other information requested in FDA's information package for Accredited Persons.

FDA may not be able to process a 510(k) submitted by an Accredited Person if review material discussed above is not included with the submission. If information necessary for the agency's review is not included, FDA may request the additional information from the Accredited Person and intends to begin its review only after the necessary information is received.

Document Processing by FDA

Reviews by an Accredited Person, along with the associated 510(k)s, should be submitted to: CDRH Document Mail Center (HFZ-401), Attention: Accredited Person Reviews, 9200 Corporate Boulevard, Rockville, Maryland 20850 USA. Any material submitted in a foreign language should be accompanied by an English translation verified to be complete and accurate.

To ensure the integrity of the review process, all Accredited Person's review materials and 510(k)s are to be submitted directly to FDA by the Accredited Person. The CDRH Document Mail Center will route submissions to the appropriate review division in ODE within CDRH. Premarket notifications [510(k)s] reviewed and submitted by Accredited Persons are expected to

bypass the first phases of FDA's usual review process, that is, the acceptance screening and initial scientific review, and instead be routed directly to the appropriate ODE supervisory official.

FDA expects the supervisory official to rely on the record of review prepared by the Accredited Person and to conduct a brief administrative assessment to determine whether the Accredited Person's review is acceptable to FDA. This assessment will apply the same criteria as for 510(k)s reviewed entirely within FDA. FDA intends to contact the Accredited Person if the agency has questions concerning the submission. The ODE supervisory official is expected to prepare FDA's decision concerning the substantial equivalence of the device. Decision letters and other significant correspondence will be sent to the Accredited Person's contact person, who should be responsible for communicating with the submitter of the 510(k).

In the event that FDA changes the initial classification that is recommended by an Accredited Person, FDA will provide a statement explaining the reasons for the change to the Accredited Person and the person who submitted the 510(k). Pursuant to section 523 (a)(2) of the act, FDA is required to make a determination in 30 days following receipt of a 510(k) recommendation from an Accredited Person.

Confidentiality of Information

Pursuant to section 523 (b)(3) of the act, an Accredited Person is required to preserve and protect the confidentiality of all information provided to it by a manufacturer or by FDA. Except for disclosure to authorized FDA employees, or as otherwise required by Federal or State law, no information pertaining to any review, including its existence, is to be made available to any person without the express written consent of the person who submitted such information to the Accredited Person.

The releasability of review information submitted to FDA by Accredited Persons will be determined by FDA in accordance with the agency's regulations implementing the Freedom of Information Act (21 CFR part 20) and §807.95 regarding confidentiality of information in 510(k)s. In general, 510(k) reviews submitted by Accredited Persons (like reviews conducted by FDA staff) will be available for disclosure by FDA after the agency has issued a substantial equivalence decision for a device, unless the information is exempt from public disclosure under part 20 or §807.95. If necessary, a copy of the 510(k) will be provided to the manufacturer for predisclosure notification pursuant to §20.61.

In addition, information submitted by an Accredited Person to obtain approval for participation in the program will be available for disclosure by FDA, unless exempt under part 20.

Records

Pursuant to section 704 of the act an Accredited Person must, at a minimum, maintain records that support its initial and continuing qualifications to be an Accredited Person. These records include:

1) documenting the training qualifications of the Accredited Person and the employees of the Accredited Person;

2) the procedures used by the Accredited Person for handling confidential information;

3) the compensation arrangements made by the Accredited Person; and

4) the procedures used by the Accredited Person to identify and avoid conflicts of interest.

In accordance with section 704 (f)(1), these records must be available upon request by an officer or employee of FDA at all reasonable times and may be viewed, copied, or verified as part of FDA's performance auditing to ensure that Accredited Persons will continue to meet the standards of accreditation or in connection with agency review or auditing of a particular 510(k) review. Within 15 days of receipt of a written request from FDA, the Accredited Person shall make copies of the requested records available at the place designated by FDA.

In addition, FDA expects Accredited Persons to retain for a reasonable period of time, but no less than three years following submission of a review to FDA:

1) copies of all 510(k) reviews and associated correspondence;

2) information on the identity and qualifications of all personnel who contributed to the technical review of each 510(k); and

3) other relevant records.

Fees Assessed by Accredited Persons

Accredited Persons may assess a reasonable fee for their services. The fee for a 510(k) review is a matter to be determined by contract between the Accredited Person and the manufacturer, but will be considered by FDA to present a conflict of interest if it is contingent or based upon the type of recommendation made by the Accredited Person. The receipt of a bribe in any form is a prohibited act under 21 U.S.C. 331(y)(3).

III. Format and Content of Accredited Person Application

Persons must apply to the Third Party Review Board (TPRB) in order to be Accredited Persons under section 523 of the act. FDA is required to respond to a request for accreditation within 60 days of receiving an application.

If a person is currently accredited under section 523 of the act and seeks to expand that accreditation to review additional device types under the program expansion described on page 6 of this guidance, the person need only submit: 1) information identifying the additional devices that the person seeks to review (e.g., all eligible devices for a specified classification panel or, if seeking to review a subset of eligible devices within a panel, identification of the specific devices by classification name and citation); and 2) any modifications to the documents, required in Section III C, that were made to accommodate the review of these additional devices. This includes modified policies and procedures for review of Class II devices for which device-specific guidance does not exist.

FDA will fax a date-stamped acknowledgment letter to the applicant's contact person when applications are received. The Third Party Review Board within CDRH will review these materials and respond to the applicant within 60 days of the date of the receipt of the application with one of the following: a letter of accreditation, a denial of accreditation, or a request for additional information. FDA may deny a request for accreditation if it determines that the applicant does not meet the criteria established for Accredited Persons in the May 22, 1998, FEDERAL REGISTER notice. FDA may deem incomplete and deny a request for accreditation if an applicant fails to respond to a request for additional information in a timely manner. Applicants may make a written request to the Director, Office of Health and Industry Programs (OHIP), CDRH, for reconsideration of a decision to deny a request for accreditation or withdraw accreditation.

The following information should be included in an application to demonstrate that a prospective Accredited Person meets the qualifications addressed in Section III B, Qualifications of Accredited Persons.

A. Administrative Information

1) Name and address of the person seeking accreditation;

2) Telephone number and FAX number of the contact person. The contact person should be responsible for addressing questions regarding the content of the application and the person to whom a letter of determination and general correspondence will be directed;

3) Name and title of the most responsible individual at the firm. Foreign applicants should also identify the name, address, telephone number, and FAX number of an authorized representative located within the United States who will serve as the Accredited Person's contact with FDA;

4) Brief description of applicant, including: type of organization (e.g. not-for-profit institution, commercial business, other type of organization); size of organization (number of employees); number of years in operation; nature of work (e.g. testing or certification laboratory); and information regarding ownership, operation, and control of organization sufficient to assess its degree of independence from device manufacturers and distributors.

5) Listing of any National, State, local, or other accreditations; and

6) List identifying the devices the applicant seeks to review. Applicants should identify the devices by classification name and citation or by classification panel if seeking to review a subset of eligible devices.

B. Prevention of Conflicts of Interest

An applicant should submit a copy of the written policies and procedures it has established to ensure that the Accredited Person and its employees (including contract employees) involved in the evaluation of 510(k)s are free from conflicts of interest, and to ensure prevention of any individual or organizational conflict of interest or appearance of conflict of interest that might affect the review process.

FDA will assess these written policies and procedures to ensure that the most common concerns relating to potential conflicts of interest are addressed.

C. Personnel Qualifications

The FDA will consider several factors with respect to personnel qualifications and the preparedness of the applicant to conduct technically competent reviews. These factors should be documented in the application and include:

1) the written policies and procedures established to ensure that 510(k)s are reviewed by qualified personnel;

2) the written instructions for the duties and responsibilities of the applicant's personnel with respect to 510(k) reviews;

3) the written personnel qualification standards established by the applicant to ensure that designated personnel are qualified in all of the scientific disciplines addressed by the 510(k)s that the Accredited

Person accepts for review;

4) the documentation (e.g. CVs) to establish that the reviewers of 510(k)s and other involved non-supervisory personnel meet the applicant's established criteria for qualified personnel. This includes documentation of education, training, skills, abilities and experience, including specialized education and experience needed for the review of Class II devices the Accredited Person accepts for review;

5) the documentation (e.g. CVs) to establish that the supervisor(s) of 510(k) reviewers have sufficient authority and meet the applicant's established criteria for qualified supervisory personnel. This includes documentation of education, training, skills, abilities and experience, including any specialized education and experience needed to supervise the review of Class II devices the Accredited Person accepts for review; and

6) the applicant's management structure or, if the applicant uses a contractor for 510(k) reviews, the contractor's management structure. The application should describe the position of the individual(s) providing supervision within the management structure and explain how that structure provides for the supervision of the 510(k) reviewers and other personnel involved in the review process.

D. Certification/Agreement Statement

A commitment, signed by the most responsible individual at the firm, to certify that the Accredited Person, at a minimum, will:

1) certify that reported information accurately reflects data reviewed;

2) limit work to that for which competence and capacity are available;

3) treat information received, records, reports, and recommendations as proprietary information;

4) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

5) protect against the use of any officer or employee of the Accredited Person who has a financial conflict of interest regarding the device, and annually make available to the public disclosures of the extent to which the Accredited Person, and the officers and employees of the Accredited Person have maintained compliance with requirements relating to financial conflicts of interest.

E. Certification/Training

The application should include a statement signed by the most responsible individual at the firm that they will have designated employees attend FDA training for Accredited Persons.

F. Facilities

The application should identify the applicant's equipment available to interface with FDA's electronic data systems (e.g. computer system with a modem, an independent FAX).

IV. Obtaining Additional Information

Information on the aforementioned documents related to FDAMA can be obtained through the FDA or CDRH Home Page and/or on 3.5" IBM formatted disks. To request a copy of these documents on disk, FAX a request to the Division of Small Manufacturers Assistance, Attention: Publications at 301-443-8818.

Also, persons interested in obtaining a copy of the documents may do so using the World Wide Web (www). CDRH maintains an entry on the World Wide Web for easy access to information, including text, graphics, and files that may be downloaded to a PC with access to the Web. The FDA Home Page may be accessed at **http://www.fda.gov** and the CDRH Home Page may be accessed at **http://www.fda.gov/cdrh**. Currently available documents for third party programs under FDAMA are listed below:

The following documents are available through FDA/CDRH Home Pages:

1) FDAMA and related documents (http://www.fda.gov/cdrh/modact/modern.html under "FDAMA" menu item)

2) (also available on disk) Premarket Notification 510(k) Regulatory Requirements for Medical Devices (August, 1995) (http://www.fda.gov/cdrh/manual/510kprt1.html)

3) (also available on disk) In Vitro Diagnostic Products: Guidance for the Preparation of 510(k) Submissions (January, 1997) (http://www.fda.gov/cdrh/manual/ivdmanul.html)

4) Third Party Review Instruction Manual (July 1, 1996) (http://www.fda.gov/cdrh/dsma/3previewmanual.pdf)

5) Determination of Intended Use for 510(k) Devices - Guidance for Industry and CDRH Staff (January, 1998) (http://www.fda.gov/cdrh/modact/k981.html)

6) Guidance on the Recognition and Use of Consensus Standards (February, 1998)(http://www.fda.gov/cdrh/modact/fr0225af.html)

7) Guidance on the Use of Standards in Substantial Equivalence Determinations (March, 2000) (http://www.fda.gov/cdrh/ode/guidance/1131.html)

V. Contact Person

For further information contact: John Stigi, Center for Devices and Radiological Health (HFZ-220), Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850, 301-443-6597 (telephone) or 301-443-8818 (FAX) regarding FDAMA Accredited Persons Program.